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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,097	10/31/2003	Edward H. Overstreet	AB-378U	9705
23845	7590	06/13/2005		
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			EXAMINER FAULCON JR, LENWOOD	
			ART UNIT 3762	PAPER NUMBER
DATE MAILED: 06/13/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,097

Applicant(s)

OVERSTREET ET AL.

Examiner

Lenwood Faulcon, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/16/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 7, 10-12, 14, 16-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter et al. (U.S. Patent No. 6,205,360).

Carter et al. teaches of an apparatus and method for automatically determining stimulation parameters, which comprises delivering electrical stimulus signals and sensing the physiological response to the applied stimulation, in order to determine the appropriate operating mode of the device (col. 2 lines 66-67, col. 3 lines 1-13). Carter et al. further teach of the use of an electrically measured neural response as a direct input to define the dynamic range of an auditory prosthesis (col. 4 lines 11-14). Carter et al. also teaches that the stimulation can be delivered by a number of channels (col. 6 lines 5-6), with multiple electrode contacts (col. 6 lines 5-10). Carter et al. further teaches of the use of a reference electrode in measuring the evoked action potential of the auditory nerve and the electrical activity of the stapedius (col. 6 lines 10-19). Carter et al. also teaches of a single stimulation pulse being applied to a particular channel (col. 7 lines 29-30), which inherently causes electrode contacts in the same channel to simultaneously deliver electrical stimuli, or inherently causes electrode contacts in different channels to sequentially deliver electrical

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stimuli. Carter et al. further teaches of reducing obscuring effects of random noise (col. 8 lines 7-13).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6, 8-9, 13, 15, 18 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (U.S. Patent No. 6,205,360) as applied to claims 1-4, 7, 10-12, 14, 16-17 and 19 above, and further in view of Doyle (U.S. Patent No. 6,175,767).

Doyle teaches of a multichannel implantable inner ear stimulator that modulates channel streaming with audio information to produce hearing for the profoundly deaf or those with other hearing impediments (col. 7 lines 24-24). Doyle further teaches of adjusting the gradient field generated by electrodes placed in proximity to the 8th nerve (col. 7 lines 45-51). Doyle also teaches of plotting the threshold intensity that is just capable of exciting an axon and its relationship to the duration of the stimulus current (col. 12 lines 49-61).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Carter et al. and Doyle to have implantable multichannel cochlear implant that forms a contour plot of intensity levels associated with electrodes at which the first evoked action potential. Carter et al. and Doyle both teach of multichannel implantable hearing devices, and thus teach of analogous arts. It would have

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been obvious to one having ordinary skill in the art at the time of the invention to modify the system and method as taught by Carter et al. by including a contour of intensity levels associated with electrode contacts at which the evoked potential is first observed as taught by Doyle in order to define stimulation parameters for use in the implanted system, since plots are commonly used to determine parameters. It would have been obvious to make such a modification to Carter et al. since Carter et al. teaches of using a sensor communicating with a processor that also communicates with a memory to provide values for stimulation parameters, and teaches of determining the threshold stimulation level for at least one stimulation mode of the system (col. 3 lines 14-28). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Carter et al. and Doyle to have the limitations of claims 5-6, 8-9, 13, 15, 18 and 20.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claims 1-20 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-6 of copending Application No. 10/698098. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a neurostimulator implant system that applies electrical stimulation to the tissue of a patient by multiple electrode contacts, adjusting the intensity of the applied electrical stimulus to which the first presence of an evoked compound action potential is detected, determining the intensity threshold level, creating a contour of intensity levels for use in defining operational parameters of the neurostimulator implant system.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Faltys et al. (U.S. Patent No. 5,626,629), Nygard et al. (U.S. Patent No. 5,758,651), Ren et al. (U.S. Patent No. 5,776,179), Faltys et al. (U.S. Patent No. 6,157,861), Overstreet (WO 03/015863), Faltys (U.S. 10/218,616).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lenwood Faulcon, Jr.



George Manuel

Primary Examiner